

REMARKS/ARGUMENTS

This Amendment is in response to the Office Action mailed July 19, 2006. Claims 1-45 were pending in the present application. This Amendment amends claims 1, 5-16, and 19-35, and cancels claims 2-4, 17-18, and 36-45, leaving pending in the application claims 1, 5-16, and 19-35. Reconsideration of the rejected claims is respectfully requested.

I. Objection to the Claims

Claim 13 is objected to as containing the informality of being dependent upon itself. Claim 13 as amended depends from independent claim 1, such that the informality has been removed. This amendment is supported by the specification and does not add new matter. Applicants therefore respectfully request that the rejection with respect to claim 13 be withdrawn.

II. Rejection under 35 U.S.C. §103

Claims 1-5, 7, 8, 13, 15-19, 21, 22, 27, 29 and 35 are rejected under 35 U.S.C. §103(a) as being obvious over *Vining* (US 6,272,366). Applicants respectfully submit that *Vining* does not teach or suggest each element of these claims.

For example, Applicant's claim 1 as amended recites a method of improving a virtual colonoscopy, including:

introducing orally a non-laxative material operable to reduce an attenuation signal of a patient's stool to an attenuation level below an attenuation level of a surrounding colon tissue

(*emphasis added*). Such limitations are neither taught nor suggested by *Vining*.

Vining teaches a method of creating three-dimensional renderings of structures such as a portion of a human body (col. 2, lines 26-35). In order to generate a three-dimensional image of a colon, for example, *Vining* teaches preparing the colon by cleansing the colon to eliminate feces from the colon, as any retained feces can simulate or mask small polyps (col. 8, lines 1-11). In place of, or in addition to, cleansing the colon, the patient can be fed a low-residue diet with a contrast agent such as barium for about three days, which can opacify any retained stool so that

the stool can be identified in the image and subsequently removed from the image (col. 8, lines 12-20). Such a method is discussed in paragraph [0007] in the Applicants' specification, characterizing the prior art, wherein it is stated that administering a contrast media such as barium enhances the signal of the stool, which allows the stool to be distinguished, but has the undesirable effect of causing small polyps to be missed or underestimated in size. As discussed in paragraph [0029], the patient's stool having an enhanced signal, or high attenuation signal relative to the surrounding tissue, creates a zone around the stool wherein the attenuation signal due to any nearby polyps is lost. The Applicants' invention recited in claim 1, for example, overcomes these deficiencies by introducing a *non-laxative* material operable to *reduce* an attenuation signal of a patient's stool to an attenuation level below an attenuation level of a surrounding colon tissue, so that the stool can be removed from the image and the attenuation signal of any nearby polyps can be better determined.

A CT colonoscopy such as is described in *Vining* requires a substantially clean (empty) colon. Laxatives and special diets typically are used to empty the colon. Leftover stool typically cannot be differentiated from colon tissue, even after use of such a laxative or diet. For example, *Vining* states that the "purpose of the cleansing procedure is to eliminate feces from the colon." Optimally, an "absolutely clean colon is desired prior to computed tomography (CT) scanning", as any "retained feces or fluid can simulate or mask small polyps because it is sometimes difficult to differentiate feces from the colon wall" (col. 8, lines 6-12). The purpose of laxatives is to clear the colon completely, as any change in stool density as a result of the laxatives is not sufficient to differentiate feces from colon. Stool density is not reliably or necessarily lowered, and *Vining* teaches that the use of laxatives is likely not sufficient due to "small amounts of retained feces" (col. 8, lines 10-12).

Vining thus teaches the addition of a contrast agent such as barium, as discussed above. Barium is a heavy element with atomic number Z 56 (relative to Z 1 for hydrogen and Z 8 for oxygen), and opacifies stool by elevating the absorption, e.g., increasing the HU number. As discussed above, such an increase is deleterious as it can result in underestimating the size of nearby polyps. It therefore is desirable to instead *reduce* the HU number. Barium, no matter how much it is diluted, increases the HU number and attenuation signal in CT imaging. Since

surrounding colon tissue has substantially the attenuation of water, diluting the barium with water still results in a diluted mixture that has a higher attenuation than the colon tissue. Even barium diluted in water can only increase the attenuation in stool.

As *Vining* does not teach or suggest introducing orally a non-laxative material operable to reduce an attenuation signal of a patient's stool to an attenuation level below an attenuation level of a surrounding colon tissue as required by Applicants' claim 1 as amended, *Vining* cannot render obvious Applicants' claim 1 or the claims that depend therefrom. Independent claims 16 and 35 recite limitations that similarly are neither taught nor suggested by *Vining*, such that these claims and the claims that depend therefrom also cannot be rendered obvious by *Vining*.

Claims 9, 10, 23, and 24 are rejected under 35 U.S.C. §103(a) as being obvious over *Vining* in view of *Pelham* (US Pub. No. 2004/0191213). These claims depend from claims 1 or 16, which are not rendered obvious by *Vining* as discussed above. *Pelham* does not make up for the deficiencies in *Vining* with respect to these claims.

Pelham teaches administering *laxatives* to cleanse bowels for diagnostic or surgical procedures (paragraphs [0030]-[0034]), and is cited as teaching that laxatives produce gas (OA p. 3). *Pelham* does not teach or suggest, however, a *non-laxative* material operable to *reduce an attenuation signal* of a patient's stool to an attenuation level below an attenuation level of a surrounding colon tissue as required by Applicants' claims 1 and 16 as amended, such that *Pelham* cannot render obvious these claims, or the claims that depend therefrom, either alone or in combination with *Vining*.

Claims 6 and 20 are rejected under 35 U.S.C. §103(a) as being obvious over *Vining* in view of *Tournier* (US 6,042,809). These claims depend from claims 1 or 16, which are not rendered obvious by *Vining* as discussed above. *Tournier* does not make up for the deficiencies in *Vining* with respect to these claims.

Tournier teaches an injectable MRI contrast composition (col. 2, line 64-col. 3, line 13), and is cited as teaching the use of a contrast gas for imaging (OA pp. 3-4). *Tournier* does not teach or suggest, however, a *non-laxative* material operable to *reduce an attenuation signal* of a

patient's stool to an attenuation level below an attenuation level of a surrounding colon tissue as required by Applicants' claim 1 and 16 as amended, such that *Tournier* cannot render obvious these claims, or the claims that depend therefrom, either alone or in combination with *Vining*.

Claims 11, 12, 25, and 26 are rejected under 35 U.S.C. §103(a) as being obvious over *Vining* in view of *Pelham* and *Tournier*. These claims depend from claims 1 or 16, which are not rendered obvious by *Vining*, *Pelham*, and/or *Tournier* as discussed above. As such, these claims also cannot be rendered obvious.

Claims 13, 14, 27, and 28 are rejected under 35 U.S.C. §103(a) as being obvious over *Vining* in view of *Lefere* (US Pub. No. 2005/0175542). These claims depend from claims 1 or 16, which are not rendered obvious by *Vining* as discussed above. *Lefere* does not make up for the deficiencies in *Vining* with respect to these claims.

Lefere teaches a colonic residue tagging system, using suitable tagging agents such as "barium-based compounds" or "iodine-based compounds" (paragraphs [0021], [0027]), which as discussed above increase the HU and attenuation signal of the stool. *Lefere* is cited as teaching that the tagging agent impregnates the stool non-homogeneously and that the greater fluid presence lowers the HU of the stool (OA p. 4). *Lefere* teaches that the greater fluid presence lowers the *concentration of the tagging agent*, thereby rendering a lower HU number that would otherwise be obtained with an undiluted tagging agent (paragraph [0048]). The tagging agent in *Lefere* increases the HU number of the stool, such that is desirable to reduce the density of the *tagging agent* in order to reduce the amount of *increase* in HU number due to the tagging agent. There is no teaching or suggestion in *Lefere* that simply adding fluid to stool will reduce the HU number of the stool. Further, adding fluid (e.g., water as found in the colon) to stool can only result in a density that is close to, but higher than, water, as the addition of cannot lower the density of stool to a density lower than that of water itself.

Lefere does not teach or suggest a *non-laxative* material operable to *reduce an attenuation signal* of a patient's stool to an attenuation level below an attenuation level of a surrounding colon tissue as required by Applicants' claim 1 and 16 as amended, such that *Lefere*

cannot render obvious these claims, or the claims that depend therefrom, either alone or in combination with *Vining*.

Claims 30, 31, and 33 are rejected under 35 U.S.C. §103(a) as being obvious over *Lefere*. Claim 30 as amended recites a non-laxative material that results in an attenuation signal of a patient's stool being lower than the attenuation signal of surrounding colon tissue, which is neither taught nor suggested by *Lefere* as discussed above. As such, *Lefere* cannot render obvious claim 30 or the claims that depend therefrom.

Claim 32 is rejected under 35 U.S.C. §103(a) as being obvious over *Lefere* in view of *Becker* (US 4,568,557). Claim 32 depends from claim 30, which is not rendered obvious by *Lefere* as discussed above. *Becker* does not make up for the deficiencies in *Lefere* with respect to Applicants' claims 30 or 32.

Becker teaches increasing the dietary fiber content in snack food (col. 3, lines 1-32), and is cited as teaching using fat as part of a laxative (OA p. 5). *Becker* does not, however, teach or suggest a *non-laxative* material operable to *reduce an attenuation signal* of a patient's stool to an attenuation level below an attenuation level of a surrounding colon tissue as required by Applicants' claim 30 as amended, such that *Becker* cannot render obvious claims 30 or 32, either alone or in combination with *Lefere*.

Claim 34 is rejected under 35 U.S.C. §103(a) as being obvious over *Lefere* in view of *Pelham*. Claim 34 depends from claim 30, which is not rendered obvious by *Lefere* as discussed above. *Pelham* does not make up for the deficiencies in *Lefere* with respect to Applicants' claims 30 or 34. *Pelham* does not teach or suggest a *non-laxative* material operable to *reduce an attenuation signal* of a patient's stool to an attenuation level below an attenuation level of a surrounding colon tissue, as discussed above, such that *Pelham* cannot render Applicants' claims 30 and 34 obvious either alone or in combination with *Lefere*.

Claims 36, 37, and 41 are rejected under 35 U.S.C. §103(a) as being obvious over *Bani-Hashemi* (US 5,647,360). Although Applicants do not agree with the rejections, these claims have been canceled from the application such that the rejections are now moot.

Claims 38-40 and 42-44 are rejected under 35 U.S.C. §103(a) as being obvious over *Bani-Hashemi* in view of *Mattrey* (US Pub. No. 2002/0061280). Although Applicants do not agree with the rejections, these claims have been canceled from the application such that the rejections are now moot.

Claim 45 is rejected under 35 U.S.C. §103(a) as being obvious over *Bani-Hashemi* in view of *Lefere*. Although Applicants do not agree with the rejections, this claim has been canceled from the application such that the rejection is now moot.

Applicants therefore respectfully request that the rejection with respect to pending claims 1, 5-16, and 19-35 be withdrawn.

III. Amendment to the Claims

Unless otherwise specified, amendments to the claims are made for purposes of clarity, and are not intended to alter the scope of the claims or limit any equivalents thereof. The amendments are supported by the specification and do not add new matter.

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Amdt. dated October 18, 2006
Reply to Office Action of July 19, 2006

PATENT

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925.472.5000.

Respectfully submitted,



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